IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

UNITED STATES OF AMERICA *ex rel.* RIBIK, Plaintiffs, v. HCR MANORCARE, INC., *et al.*, Defendants.	CIVIL ACTION NUMBER: 1:09-cv-0013 (CMH/TCB) (Lead Case)

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

The United States Department of Justice ("DOJ") alleges four affiliated corporate Defendants (collectively, "HCRMC") defrauded Medicare by forcing tens of thousands of unnamed licensed clinicians working in over 270 skilled nursing facilities indirectly owned by one or more of the Defendants ("Defendants' SNFs" or "the SNFs") over a six year period to deliver unnecessary rehabilitation therapy to patients.[1] But what DOJ really alleges is as follows, (1) a patient who received 60 minutes of physical therapy on a particular day should only have received 45 minutes, (2) electrical stimulation that was provided to a patient should not have been reimbursed because the therapist did not record the strength of the electrical impulse, (3) group therapy that was provided to a patient should not have been reimbursed because the therapist did not record specifically what occurred in the group session as opposed to what occurred in an individual session, and (4) speech therapy provided to a patient should not have been reimbursed because it was for cognitive purposes only, not swallowing. But wait, all of these claims were originally paid by Medicare's contractors who are responsible for reviewing and processing claims in the normal course of HCRMC's business. And none of these alleged payment criteria invented by DOJ and its alleged expert exist anywhere in writing, nor did any Medicare Contractor ever apply any such rules in processing and paying the SNFs' Medicare claims. To be clear, DOJ has no evidence that any of the contractors who processed the SNFs' Medicare claims ever down-coded or denied any claim based on these litigation-invented criteria. And the reason is obvious, it is because these alleged criteria do not exist in the real-

[1] The named defendants are HCR ManorCare, Inc., Comp. ¶ 26, Manor Care, Inc., alleged to be the predecessor of HCR ManorCare Inc., Comp. ¶ 27, HCR Manor Care Services, LLC, a company alleged to provide services to the SNFs, Comp. at ¶ 29, and Heartland Employment Services, LLC, alleged to provide employees to the parent corporation and the SNFs, Comp. ¶ 28. DOJ did not name as defendants any individual SNF or any employee.

world, they exist only in the mind of DOJ and its alleged expert.

But it gets even worse. DOJ has not identified a single corporate officer of HCRMC who ordered, participated in, or had knowledge of any fraud. DOJ did not question or depose the CEO who managed HCRMC during the relevant time period, and he denies any such fraud. Every officer and manager deposed in the case denied any such fraud. And, DOJ concedes that the thousands of physicians who ordered, certified and re-certified the therapy did not commit any fraud, and none were identified by DOJ as witnesses. Faced with these fatal problems, and unwilling to concede the truth that there was no fraud, DOJ proposes a trial exclusively dependent on alleged expert testimony to prove fraud related to a subset of patients. Specifically, DOJ intends to introduce evidence relating to claims for 180 sample patients (the "180 Patient Sample"). To establish a false claim DOJ must prove that a treating therapist knowingly over-delivered therapy to a patient in the sample. But DOJ has not identified a single treating therapist who will testify to this. Nor has DOJ identified a single document connected to the treatment of any of the 180 pages to prove this. Further, even its own expert admits that she cannot testify as to whether a claim was false. These material facts are not in dispute.

Then, DOJ proposes to do what no federal court in a False Claims Act ("FCA") case based on medical necessity has ever done, that is, allow a jury to hear expert testimony to extrapolate liability and damages to over 200,000 Medicare patients. There is no genuine dispute of material fact about these or any other issues, and as such this case is ripe for summary judgment. *See Mars, Inc. v. The J.M. Smucker Co.*, Case No. 16-cv-01451, 2017 WL 4323582, *1 (E.D. Va. Sept. 27, 2017).

To reach trial, the Court would have to allow DOJ to unilaterally change the Medicare reimbursement system for the relevant time period. Apart from adjustments required by

evolving Medicare regulations, Defendants' SNFs have planned, delivered, and been paid, and continue to be paid, by Medicare for rehabilitation therapy in the same manner for the time periods both before and after the relevant time period of the Complaint (October 2006 – May 2012). Ex. 1, Cavanaugh Dep. 466:4-467:6; 485:16-488:9, 490:14-491:21. There was no systematic reduction in therapy after HCRMC became aware of this lawsuit in 2013 or after DOJ intervened in 2015. *Id*. In sum and substance, this case is about DOJ applying its own after-the-fact made-for-litigation payment criteria to claims submitted during an arbitrarily selected six year period that were never applied by CMS or its contractors in the operation of the Medicare system. There is no evidence that these made-for-litigation criteria exist outside of this case, nor is there any evidence that the Defendants were aware of these criteria because knowledge of things that do not exist is legally impossible.

DOJ has one witness upon whom this case rests, Rebecca Clearwater, an alleged expert who works for Medicare contractor AdvanceMed. AdvanceMed is not authorized to process Medicare claims, instead it investigates alleged fraud. Clearwater's unsupported and unreliable opinions are the only evidence that some of the SNFs delivered some therapy that was not reasonable and necessary to a subset of the 180 Patient Sample. This conclusion follows from her review of a biased sample of just 180 of the over 500,000 Medicare patients treated during the relevant time period. But Clearwater, notwithstanding clear legal requirements, was never authorized by the Secretary of Health and Human Services to render claims decisions in this case. 42 U.S.C. § 1395ddd(a)-(b). Nevertheless, she generally denied or down-coded group therapy, modalities, speech language pathology and therapy minutes on individual days based on the subjective application of made-for-litigation criteria that are written nowhere, alleged ethereal practice standards which she failed to produce, none of which were ever applied by any

Medicare Contractor to HCRMC's SNFs' claims.

DOJ has not identified a single clinician, of the thousands who treated the 180 patients in the sample, who will say s/he delivered unreasonable and unnecessary services to any one of these patients. While DOJ has grossly mischaracterized without evidence a small number of documents it thinks prove there was corporate pressure to deliver more therapy, there is no evidence linking a single one of these documents to any of these 180 patients, nor is there any testimony (that is, words coming out of a witness's mouth as opposed to the questions posed by DOJ lawyers) that any of these documents are evidence of the alleged fraud. And while the Complaint makes clear that the individual SNFs filed the claims for reimbursement, *see* Comp. ¶¶ 62, 63, 65, DOJ has not identified a single individual working in a single SNF who was involved in any manner in delivering the therapy or filing any claims for the sample patients as having committed any fraud. Instead, DOJ claims without evidence that someone working at the corporate Defendants (it is not clear who), far removed from patient care and clinical decisions, somehow overwhelmed the clinical decision-making of tens of thousands of licensed medical professionals causing unnamed therapists to delivery unnecessary therapy and causing unnamed administrative employees to file corresponding claims knowing the claims were for unnecessary and unreasonable therapy.

DOJ says that the alleged falsity is contained in Minimum Data Set ("MDS") and CMS 1450 claim forms filed by the SNFs. But all of these documents are factually correct and accurately report the types and amounts of therapy that was delivered. DOJ invents that the forms were "false" because some of the therapy was allegedly not reasonable and necessary, despite the fact that neither the MDS nor the CMS 1450 contains any such certification.

There is no genuine dispute about any material fact relating to the complete absence of

evidence of objective falsity, scienter and materiality as follows:

First, there is no evidence that any Defendant told an objective falsehood, that is, a lie. *See U.S. ex. rel. Wilson v. KBR*, 525 F.3d 370, 376-7 (4th Cir. 2008). DOJ has produced no evidence of the correct amount of therapy for any specific patient because no such evidence exists. Ex. 2, Fries Dep. 411:17-20. The MDS and CMS 1450 claims forms correctly reported the type and amount of therapy that was delivered. These therapy types and amounts were based on reasonable treating clinicians' interpretations of ambiguous regulations which are not subject to an objective standard. *See U.S. ex. rel. Purcell v. MWI*, 807 F.3d 281, 288 (D.C. Cir. 2015) (whether a regulation is ambiguous and whether a defendant's interpretation of that ambiguous regulation was objectively reasonable are purely questions of law). Moreover, after-the-fact clinical disagreements between the treating clinicians and an alleged DOJ expert cannot constitute falsity as a matter of law. *See U.S. ex. rel. Morton v. A Plus Benefits, Inc.*, 139 Fed. Appx. 980, 983 (10th Cir. 2005); 42 C.F.R. § 483.20(j)(2).

Second, there is no evidence that any Defendant or any of the SNFs acted with the scienter required by the FCA. There is no evidence that any employee of any of the Defendants knew excessive therapy had been provided to any of the 180 patients in the sample. Moreover, there is no evidence that any of the corporate Defendants or SNFs knew about the alleged DOJ expert's *post hoc* subjective payment criteria when the SNFs submitted the claims at issue.

Third, there is no evidence that any purported false statements were material to the government's decision to pay the claims at issue. *See Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). The record shows that the government knew about what DOJ now alleges was the SNFs' provision of unreasonable and unnecessary therapy in 2006, three years before relator Ribik filed her suit and nine years before DOJ intervened. Yet over

those nine years, the government continued to pay the hundreds of thousands of claims DOJ now alleges violate the FCA.[2]

Fourth, there is no evidence that any of the named Defendants made any claims for payment or filed any documents connected to reimbursement for the sample patients. All such claims were filed by the SNFs which each had their own Medicare Provider number. DOJ has not identified or provided evidence of any corporate officer who had the requisite knowledge and intent regarding the claims in the 180 Patient Sample, or any other patient-specific claims. *See U.S. v. Sci. Applications Int'l Corp*., 626 F.3d 1257, 1274 (D.C. Cir. 2010) (collective knowledge is an inappropriate basis for proof of scienter in an FCA case).

Fifth, DOJ's intent to prove false claims outside the 180-patient sample would require the Court to allow FCA liability based solely on statistical extrapolation, thus negating, as a matter of law, the requirement that materiality and scienter requirements be strictly enforced. *See Escobar*, 136 S. Ct. at 2001-02.

Sixth, as a matter of law, DOJ cannot rely on the *Ribik* complaint to toll the running of the statute of limitations and, consequently, the statute of limitations has run on any claims for payments filed before April 10, 2009 (six years prior to filing of Complaint in Intervention).

This complete failure concerning essential elements of DOJ's case renders all other facts immaterial. *See Haulbrook v. Michelin N. Am.*, 252 F.3d 696, 702 (4th Cir. 2001); *Mars, Inc.*, 2017 WL 4323582 at *3 (evidence failed to create genuine dispute where it was "largely irrelevant" to the underlying theory of liability). As such Defendants respectfully request that summary judgment be granted. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 585-6 (1986). In the alternative, Defendants request that partial summary judgment be

[2] DOJ's common law claims are based on the same facts that underlie the DOJ's FCA claims, so the common law claims fail for the same reasons the FCA claims fail. *Infra* at § V.E.

granted for (1) one or more of the Defendant companies, (2) all claims not contained in the 180 Patient Sample and/or (3) for all claims filed before April 10, 2009.

II. DOJ'S CLAIMS AGAINST DEFENDANTS

DOJ alleges that from October 1, 2006 through May 31, 2012, Defendants engaged in a corporate-wide effort to over-deliver and bill Medicare for rehabilitation therapy that was not reasonable and necessary. Comp. ¶¶ 4, 6, 46-47, 168. DOJ alleges Defendants knowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval by the submission of MDS and CMS 1450 claims forms for therapy that was not reasonable and necessary and skilled. Comp. ¶¶ 62, 63, 65, 88, 216, and 219. DOJ does not allege that the therapy reported on the MDS and CMS 1450 forms was not delivered; the alleged falsity is based solely on the assertion that certain therapy was not reasonable and necessary and skilled. The Complaint does not identify any certification by any Defendant on the CMS 1450. As to the MDS, the Complaint alleges that it contains a statement by the SNF that the information was "collected" is accordance with applicable Medicare requirements and will be used for payment. *Id*. ¶¶ 62-63. DOJ also asserts two common law counts for unjust enrichment against all four Defendants and payment by mistake against only HCR Manor Care Services.

III. STATEMENT OF UNDISPUTED MATERIAL FACTS

1. HCR ManorCare, Inc., and Manor Care, Inc. operated over 270 SNFs during the time period alleged in the Complaint, October 2006 – May 2012 (the "Relevant Time Period"). Ex. 3, HCR Dep. 127:17-21.

2. To determine if services delivered by Defendants' SNFs were reasonable and necessary, DOJ used an employee of Medicare contractor AdvanceMed, Rebecca Clearwater, to review the medical charts of 180 patients from the over 500,000 Medicare beneficiaries treated during the relevant time period. Ex. 4, Defs.' Resp. to Interrog. 31. AdvanceMed was a

Program Safeguard Contractor and was not engaged by the Centers for Medicare and Medicaid Services ("CMS") to process or pay Medicare Part A claims, but rather to investigate alleged fraud. Ex. 5, Clearwater Dep. 821:15-822:15; Ex. 6, Medicare Program Integrity Manual ("MPIM"), Chapter 4, § 4.2.2 *et seq*. Clearwater never worked in the medical review department at AdvanceMed, and instead she supervised projects for DOJ. Ex. 5, Clearwater Dep. 823:21-824:1; 831:11-833:6.

3. The SNFs submitted claims for services to Medicare Administrative Contractors ("MACs") for processing and payment. Ex. 7, Decl. of Larry Young, Dkt. 430-1, ¶ 5.

4. Pursuant to the claims review system set up by CMS, if a claim is denied in whole or in part by a MAC, that determination undergoes multiple levels of review, as follows: a redetermination by a different employee of the MAC; reconsideration by a Qualified Independent Contractor ("QIC") (including review by one or more physicians); and a hearing before an Administrative Law Judge ("ALJ"). Medicare Claims Processing Manual (Pub. 100-4), Chapter 29, § 310-345; Ex. 8, Maximus Dep. 71:14-72:4; 163:7-16. Further, CMS or the Provider can seek review by the Medicare Appeals Council and a United States District Court. *Id*. At each level, the MAC, QIC and ALJ can consider position papers of the SNF to explain the medical records and the treatment, and the ALJ can receive testimony of clinicians or others. 42 C.F.R. §§ 405.946, 405.966, 405.1014. ALJ decisions that are not appealed become the final decision of the Secretary of Health and Human Services ("HHS"), and decisions that are not appealed at any lower stage become the binding decisions of the Secretary. 70 Fed. Reg. 36,386, 36,387 (June 23, 2005); 42 C.F.R. §§ 405.928(b), 405.978; 41 U.S.C. § 1395kk-1.

5. During the relevant time period, Defendants' SNFs submitted claims to three different MACs, National Government Services ("NGS"), Highmark Medicare Services

("Highmark"), and Cigna Government Services ("CGS"). Most appeals of these claims were handled by MAXIMUS Federal Services, Inc. ("Maximus"), a QIC.

6. During the relevant time period, the vast majority of MAC claims denials that were appealed by all SNF Providers were eventually reversed in favor of the Providers. Ex. 9, U.S. Resp. to Defs.' Interrog. 32.[3] As recently as August 2017, the SNFs continue to receive favorable ALJ decisions for claims originally filed during the Relevant Time Period. Ex. 10, Compilation of Recent Medicare Appeal Decisions by ALJs.

7. As early as 2000, Manor Care, Inc. began developing and implementing a post-acute care business model in which it sought to transition the focus of its SNFs from traditional long term care patients to post-acute hospital patients requiring rehabilitation therapy and shorter stays. Ex. 3, HCR Dep. 168:18-170:10; 355:6-359:1; Ex. 11 Lester Dep. 42:2-44:22; Ex. 12, Lazarus Dep. 93:3-94:2, 96:14-100:8, 126:13-130:1; Ex. 13, Pagoaga Dep. 271.17-275:14; Ex. 14, Carlyle_0001053, Ex. 293; Ex. 15 Defs.' Resp. U.S. Interrog. 9.

8. Both before and during the relevant time period, Defendant companies made significant, multi-million dollar investments to support the post-acute care model transition at their SNFs, which included improving and reorganizing facilities, hiring and training more therapists and staff, building entirely new facilities, constructing new therapy gyms, investing in electronic systems and equipment, and marketing to acute care providers. Ex. 16, Grahn Dep. 122:18-124:16; Ex. 1, Cavanaugh Dep. 225:4-228:16; 434:16-444:19; Ex. 17, Ormond Dec. ¶ 4.

9. As a result of these strategic investments, over time the SNFs were able to offer and provide care to higher acuity patients with increased skilled rehabilitation therapy needs

[3] Combined fully favorable and partially favorable reversal rates at the ALJ level were: 67.5% in 2006, 65.7% in 2007, 75.3% in 2008, 81.4% in 2009, 81.8% in 2010, 81.9% in 2011, and 70.9% in 2012.

more days per week. Ex. 18, Analyses of Average Therapy Days for Admissions Included in Fries & Morris Report, Exs. 735 and 736. The SNFs' patient mix shifted over time to more Medicare Part A and Medicare Managed Care post-hospital patients and less long-term care patients allowing the SNFs to take advantage of economies of scale with respect to its resources. Ex. 1, Cavanaugh Dep. 444:19-449:21; Ex. 19, Black Dep. 302:13-311:7; Ex. 20, Gloth Dep. 33:12-39:13, 56:5-57:15, 230:1-9; Ex. 12, Lazarus Dep., 237:13-238:16; Ex. 13, Pagoaga Dep., 271:17-275:14; Ex. 21, Russell Dep. 92:17-96:20; 315:2-317:19; 321:12-325:4; Ex. 22, Carlyle_0001059, Ex. 294 at Carlyle_0001081; Ex. 15, Defs.' Resp. to U.S. Interrogs. 8-9.

10. The Defendant companies' transition was either un-noticed or ignored by the HHS-OIG and Medicare contractors, as described in ¶¶ 14-25 below, who simply continued to investigate that certain SNFs were delivering more minutes of care than many of the other 15,000+ SNFs in the United States, which had never transitioned from long-term care to caring for post-acute patients. Ex. 1, Cavanaugh Dep. 441:15-443:17.

11. Relator Christine Ribik ("Ribik") worked as a part-time occupational therapist at three SNFs in Virginia from May to December 2004. Ex. 23, Ribik Resp. to Defs.' RFAs 4-5.

12. At some time in or about 2005, Ribik advised the HHS-OIG that certain SNFs in Virginia were providing therapy to Medicare patients that she believed was not reasonable and necessary.

13. In November 2005, after conducting an investigation of Ribik's information, the HHS-OIG informed external counsel for Defendants that there was no evidence to support Ribik's claim and the matter would be closed. Ex. 24, Transcript of voicemail message from HHS-OIG Agent Bobby Hyland.

14. In 2006, Medicare Program Safeguard Contractor ("PSC") AdvanceMed commenced audits of two of Defendants' SNFs located in Perrysburg, Ohio and Grand Rapids, Michigan. Ex. 25, US-HCRMC-01844884, US-HCRMC-01845033, US-HCRMC-01848533, US-HCRMC-01848534.

15. On October 25, 2006, the HHS-OIG [redacted] *Id*. US-HCRMC-01848534.

16. In November 2006, Medicare Contractor NGS noted in internal documents that AdvanceMed was investigating Defendants. Ex. 26, US-HCRMC-01820081.

17. On December 1, 2006, Senator Charles Grassley wrote a letter to CMS and HHS-OIG describing information provided to him by Ribik that several SNFs in Virginia, including three owned by Defendants, were filing fraudulent Medicare claims. Ex. 27, CR-609.

18. On March 27, 2007, AdvanceMed noted that [redacted]. Ex. 28, US-HCRMC-01844970.

19. On October 10, 2007, AdvanceMed documented a call from an employee of the Perrysburg SNF requesting a status of the review that began in 2006. Ex. 29, US-HCRMC-01742810. The AdvanceMed employee wrote that she [redacted]'" *Id*.

20. On October 11, 2007, the day after the telephone call referenced above, AdvanceMed employee Christina Jessee summarized her review of claims for 101 patients from the SNF in Perrysburg. Ex. 30, US-HCRMC-01745590. Jessee concluded that certain therapy

[4] AdvanceMed and HHS-OIG documents sometimes refer to certain SNFs as "Heartland," a trade name for certain Defendants' SNFs.

provided to Medicare beneficiaries was not reasonable and necessary. In hundreds of instances, group therapy and modality services were provided and were not specifically documented in the order, plan of care or weekly progress notes, but Jesse allowed these claims. Ex. 31, October 4, 2017 Jessee Declaration.

21. In March 2008, Gerri Harris of AdvanceMed, summarized the results of her medical review of claims for 132 patients submitted by the SNF in Grand Rapids. Ex. 32, US-HCRMC-01844903. She concluded that certain therapy provided to Medicare Part A beneficiaries was not reasonable and necessary, but she did not specifically deny any group therapy or modality services. Ex. 33, US-HCRMC-01749767.

22. The results of the Perrysburg and Grand Rapids audits were never communicated to any of the Defendants or their SNFs until this litigation commenced, and at the direction of DOJ, CMS never demanded any repayments. Ex. 34, US-HCRMC-01853345; US-HCRMC-01853294.

23. On May 15, 2008, more than six months before Ribik filed her complaint, AdvanceMed made a Case Referral to the HHS-OIG regarding questionable billing practices by Defendants' SNFs. Ex. 35, US-HCRMC-01745585; US-HCRMC-01844916; US-HCRMC-01844883; US-HCRMC-01745587; US-HCRMC-01745588.

24. On August 19, 2008, HHS-OIG advised AdvanceMed that the United States Attorney's Office had opened a case on the Perrysburg SNF. Ex. 36, US-HCRMC-01742589.

25. On September 10, 2008, HHS-OIG advised AdvanceMed that the Grand Rapids SNF would be further investigated by HHS-OIG. Ex. 37, US-HCRMC-01742809.

26. On January 7, 2009, over four years after ceasing to work for any of the SNFs, Ribik filed her Complaint, repeating the exact same information she had provided to the HHS-OIG in 2005 and to Senator Grassley in 2006. Ribik Compl. (Dkt. 1).

27. On March 10, 2009, DOJ filed under seal its first extension of time to keep the Ribik Complaint under seal. Ex. 38, United States' Unopposed *Ex Parte* Application for a First Extension of Time to Consider Election to Intervene ("Extension Filing"), Mar. 9, 2009. DOJ did not inform the Court that (1) Relator Ribik had originally provided the exact same information to the government 4-5 years earlier, (2) AdvanceMed and the HHS-OIG had been investigating Defendants' SNFs for over three years (since 2006) regarding similar allegations in Ribik's complaint, or (3) that the U.S. Attorney's Office in Toledo, Ohio had been investigating allegations of the same type since mid-2008.

28. On May 11, 2009, an internal AdvanceMed document stated that DOJ Civil Fraud Section Supervisor Andy Mao, whose name appears on this case, [redacted] Ex. 39, US-HCRMC-01853334.

29. On September 4, 2009, DOJ submitted its second request for an extension of the seal for the Ribik Complaint. Ex. 40, Extension Filing, Sept. 4, 2009. DOJ stated that [redacted] DOJ also stated that it [redacted]" DOJ did not advise the Court that just two days prior it had issued its first subpoena in the case, to a single SNF in Virginia. Ex. 41, Sept. 2, 2009 HHS-OIG Subpoena to ManorCare – Fair Oaks. DOJ also failed to advise the Court that the only witness interview it had conducted in the eight months since Ribik filed her complaint was with Ribik herself. Ex. 42, Ex. A to U.S. Am. Resp. to Defs.' Interrog. 8.

30. On November 4, 2009, AdvanceMed emailed DOJ lawyer Jill Callahan to ask about the status of the DOJ investigation; Callahan responded that she [redacted]." Ex. 43, US-HCRMC-01845123

31. On March 29, 2010, fifteen months after Ribik filed her complaint, Callahan advised AdvanceMed that her [redacted] Ex. 44, US-HCRMC-01845097. At no time did DOJ ever advise the Court of the delays due to lack of resources.

32. In July 2010, AdvanceMed's Deputy Program Director wrote that [redacted] Ex. 45, US-HCRMC-01845233-38. She went on to write that [redacted]ain." *Id*. at US-HCRMC-01845236.

33. On September 3, 2010, almost 2 years after Ribik filed her complaint, DOJ requested that AdvanceMed perform a medical record review of ten patient files from four SNFs. Ex. 46, US-HCRMC-01853387. These patient files are not part of the 180 Patient Sample. *Compare* Ex. 46, US-HCRMC-018553387 *with* Ex. 47, App. C to U.S. Discovery Requests (identifying patients in 180 Patient Sample).

34. On September 7, 2010, DOJ filed its fourth request for an extension of the seal. Ex. 48, Extension Filing, Sept. 7, 2010. DOJ represented to the Court that it [redacted]

[redacted] DOJ did not advise the Court that it had only requested medical records for 10 patients, had not done so until August 19, 2010, and had not requested AdvanceMed review those records for potential fraud until September 3, 2010, just 4 days prior to their extension request.

35. On March 4, 2011, DOJ filed its fifth request for an extension of the seal. Ex. 49, Extension Filing, Mar. 4, 2011. DOJ noted that it had [redacted]. DOJ failed to advise the Court that the alleged additional allegations had been known to the government for six years.

36. On April 26, 2011, Ribik filed her Amended Complaint, in which she named all Defendants' SNFs as individual defendants, but added no substantive allegations to the original complaint. Dkt. 23.

37. On April 29, 2011, the HHS-OIG advised AdvanceMed there is [redacted]. Ex. 50, US-HCRMC-01844862.

38. On July 29, 2011, two and a half years after Ribik filed her complaint, AdvanceMed completed the medical review of the ten patient charts that DOJ had requested in September 2010. Ex. 51, US-HCRMC-01853412-17. The review was conducted by Marna Bogan, an AdvanceMed employee who does not work in the medical review division but instead works for Clearwater. The review results make no mention of denials for group therapy, modalities, or daily minute reductions although the medical records submitted make clear that these services were provided. *Id.*[5]

[5] This document was among the documents DOJ originally withheld as attorney-client privileged, but later produced after being ordered to by the Magistrate Judge. The documents were produced on September 20, 2017, after the close of discovery and after Defendants had already deposed Ms. Bogan.

39. On September 7, 2011, DOJ filed its seventh request for an extension of the seal period. Ex. 52, Extension Filing, Sept. 7, 2011. DOJ informed the Court that in April 2011, Ribik filed her Amended Complaint. DOJ stated that "[redacted]." DOJ failed to inform the Court that the government had known of these exact same allegations of alleged corporate-wide activity as early as 2006, that is, for five years.

40. On September 28, 2011, Relator Carson filed his Original Complaint. The case was assigned to Judge Trenga. Docket No. 1:11-cv-1054 AJT/TCB.

41. In January 2013, four years after Ribik filed her Original Complaint, and over seven years after Ribik provided her information to the HHS-OIG, CMS and Congress, DOJ caused the HHS-OIG to issue its first subpoena requesting corporate records from the corporate Defendants. Ex. 53, DOJ Civil Investigative Demand 12-408 to HCR ManorCare.

42. In June 2012, to avoid Judge Trenga's May 29, 2012 order that no further extensions of the seal would be granted in the *Carson* case, DOJ consolidated the *Carson* case into the *Ribik* case so that it could attempt to keep the combined cases under seal, which it did for an additional three years. Ex. 54, Extension Filing, Sept. 6, 2012, 3 n.1.

43. DOJ filed its Complaint in Intervention on April 10, 2015, and the relevant time period of the allegations is October 1, 2006 through May 31, 2012. ECF 84 ¶ 6. DOJ did not intervene against or name as Defendants any of the individual SNFs.

44. The only evidence of falsity of any specific claim is the testimony of Rebecca Clearwater, the AdvanceMed employee who denied and down-coded claims for the patients in the 180 Patient Sample taken from Medicare Part A beneficiaries treated in certain of

Defendants' SNFs during the Relevant Time Period. She did not opine that any of the claims for these patients were "false." Ex. 5, Clearwater Dep. 797:18-19.

45. Each of the claims for the beneficiaries in the 180 Patient Sample was paid at or around the time of submission. Ex. 55, Expert Report of Don Edwards 6.

46. AdvanceMed had a vested interest in DOJ intervening in this case because it is eligible for bonus payments. Ex. 56, GAO Report to Congressional Requesters – Medicare Program Integrity, Contractors Reported Generating Savings, but CMS Could Improve Its Oversight, Oct. 2013, 12-13.

47. Clearwater's opinions were never subject to any independent review, or to review by any MAC, QIC, ALJ or Court. Ex. 5, Clearwater Dep. 799:7-8.

48. Clearwater denied almost all group therapy minutes provided to the patients in the 180 Patient Sample because in some cases the group therapy was not ordered by a physician, included in the plan of care and/or explained in weekly therapy summaries. Ex. 5, Clearwater Dep. 89:4-8, 661:7-13. Ex. 57, Clearwater Rep. 16.

49. During the time period of this case, there was no statute, regulation, or CMS guidance requiring that group therapy be ordered by a physician, included in the plan of care or explained in the weekly summary notes. Ex. 58, U.S. Resp. to Defs' RFA 42; Ex. 59, CMS Dep. 262:8-21; Ex. 5, Clearwater Dep. 525:5-530:12.

50. Further, no MAC, QIC or ALJ imposed any such requirement for reimbursement of group therapy. Ex. 60, Decl. of McKinney/NGS; Ex. 61, CGS Dep. 441:2-12; Ex. 62, Maximus Supp'l Dep. 13:14-14:2; Ex. 63, Highmark Dep., 322:17-324:3.

51. Clearwater denied almost all modality services like electrical stimulation and diathermy because in some cases the modality was not ordered by a physician, included in the

plan of care and/or explained in weekly therapy summaries, and because the medical record did not indicate the placement of electrodes, frequency and the intensity of services and documentation of beneficiary response. Ex. 57, Clearwater Rep. 19-20; Ex. 5, Clearwater Dep. 1149:2-12, 1149:20-1155:18.

52. During the time period of this case there was no statute, regulation, or CMS guidance requiring that modalities be ordered by a physician, contained in the plan of care or explained in the weekly summary notes. Ex. 8, Maximus Dep. 215:10-216:7; Ex. 59, CMS Dep. 332:10-15.

53. Further, no MAC, QIC or ALJ imposed any such requirement for reimbursement of modalities. Ex. 59, CMS Dep. 332:10-15; Ex. 60, Decl. of NGS ¶ 3(b); Ex. 63, Highmark Dep. 314:13-316:9; Ex. 8, Maximus Dep. 294:5-297:7.

54. In many instances, Clearwater denied a certain amount of daily treatment minutes because in her view the minutes provided were not reasonable and necessary. Ex. 5, Clearwater Dep. 51:2-18; 55:4-64:11; 69:14-72:15; 80:16-20; 112:9-21; 1040:4-22; 1045:16-20; 1051:17-1052:17. Clearwater failed to identify specifically which minutes, that is, which specific services, were not reasonable and necessary. *Id*. 69:14-72:15, 112:9-21.

55. There is no statute, regulation, CMS guidance or literature that sets forth the correct number of minutes for any type of patient. Ex. 5, Clearwater Dep. 515:15-516:9.

56. Further, no MAC, QIC or ALJ permitted only a certain number of minutes of therapy per day. Ex. 8, Maximus Dep. 219:5-220:15; Ex. 61, CGS Dep. 320:3-323:8; 321-325:9; Ex. 64, US-HCRMC-01807570-72, Exhibit 799.

57. In many instances Clearwater denied speech language pathology services when it was used to treat cognitive impairments, despite her testimony that speech therapy can be used to treat cognitive disorders. Ex. 5, Clearwater Dep. 850:14-851:8.

58. In three instances, Clearwater reviewed and made a decision regarding a claim that had been reviewed by a Medicare contractor in the ordinary course of the administrative claims process as set forth in ¶ 4. In each instance, Clearwater's decision was contrary to the binding or final decision of the Secretary of HHS, and as such her error rate is 100%.

59. Clearwater's decision to deny group therapy for patient [redacted] claim contradicts the decision by an ALJ that all of the services provided were covered by Medicare. Ex. 5, Clearwater Dep. 673:8-675:19; 892:19-893:14.

60. Clearwater's decision to deny group therapy and deny all services provided after May 14, 2009 for patient [redacted] claim contradicts the decision made by Maximus in March 2010. Ex. 5, Clearwater Dep. 710:5-16; 892:19-893:14.

61. Clearwater's decision to deny group therapy and deny speech language pathology services for patient [redacted] claim contradicts the decision made by Highmark in April 2009. Ex. 5, Clearwater Dep. 737:18-738:15.

62. During the relevant time period each individual SNF had its own Medicare Provider number. Each SNF through its MDS Coordinator, and in some instances with assistance of a Central Billing Office, submitted claims for skilled rehabilitation services under Medicare Part A. Ex. 15, Defs.' Resp. to U.S. Interrog. 4; Ex. 65, Defs.' Resp. to U.S. RFAs 59 & 60. DOJ has not identified any MDS Coordinator or Central Billing Office employee as having participated in the alleged fraud.

63. Medicare services for the patients in the 180 Patient Sample were generally certified, and when necessary, re-certified by physicians as requiring skilled services. DOJ concedes that Defendants did not pressure physicians to falsely order or certify the need for rehabilitation services and that no physician knowingly certified services that were unreasonable or unnecessary. Ex. 66, U.S. Am. Resp. to Defs.' RFAs 5-7. DOJ has not identified any physicians as individuals with discoverable knowledge who may support its claims. U.S. Rule 26(a)(1) Disclosures.

64. SNFs are entitled by law to rely on physician certifications that the therapy was reasonable and necessary. 64 Fed. Reg. 41,644, 41,660 (July 30, 1999). There is no testimony or documentary evidence that any clinician or employee who assessed, treated or submitted claims to Medicare for the patients in the 180 Patient Sample received any instruction or direction from any officer or employee of the Defendants to bill for unreasonable, unnecessary or unskilled services, or knew that the therapy was unreasonable, unnecessary or unskilled for those patients.

65. No corporate officer of any Defendant engaged in a scheme to bill for unreasonable or unnecessary services, to defraud Medicare or to engage in any of the alleged improper conduct in the Complaint. Ex. 17, Ormond Dec.; Ex. 67, Guillard Dec.; Ex. 68 Kang Dec.; Ex. 1, Cavanaugh Dep. 472:9-477:20; Ex. 12, Lazarus Dep. 399:1-402:11; Ex. 11, Lester Dep. 191:3-195:7; Ex. 13, Pagoaga Dep. 265:19-272:1; Ex. 69, Mastrangelo Dep. 366:10-367:8; Ex.70, Johnson Dep. 345:4-348:6; Ex. 71, Casper Dep. 356:11-358:20; Ex. 19, Black Dep. 323:17-326:7; Ex. 21, Russell Dep. 355:12-356:2; Ex. 72, Rice-White Dep . 366:5-364:16; Ex.

16, Grahn Dep. 396:1-397:7. [6] There is no testimony or documentary evidence that contradicts this testimony.

66. The SNFs operated by the Defendants incurred the costs of delivering all of the therapy provided to their patients.

67. Therapists and Directors of Rehabilitation at the SNFs who made clinical assessments of patients' needs and delivered therapy and MDS Coordinators who submitted MDS Forms were not eligible for bonuses. Ex. 3, HCR Dep. 476:13-20.; Ex. 70, Johnson Dep. 98:22-99:4; Ex. 16, Grahn Dep. 384:6-385:18; Ex. 73, Tirbany Dep. 266:10-12; Ex. 74, Obee Dep. 61:3-7.

68. The corporate Defendants implemented and maintained a corporate compliance program that prohibited Medicare fraud. Ex. 75, Dep. Exs. 409 & 410; Ex. 12, Lazarus Dep. 360:19-377:17.

69. The corporate Defendants maintained internal Standards of Business Conduct applicable to each and every employee, which prohibited Medicare fraud and were periodically updated, and all employees were required to be trained on the standards and sign a certification of completion. Ex. 76, Dep. Exs. 411-416; Ex. 12, Lazarus Dep. 360:19-377:17.

70. The Defendants required employees to annually complete a compliance training, which provided an overview of the Corporate Compliance Program, standards of business conduct, and set the expectations and rules that they expected employees to follow. Ex. 12, Lazarus Dep., 149:4-152:21; 360:19-377:17.

[6] HCRMC's senior management team consists of its CEO, COO, CFO and General Counsel. Ex. 3, HCR Dep. 477:4-15. DOJ never sought to depose former CEO Paul Ormond or CFO Matt Kang, and the deposition of former COO Stephen Guillard was cut short prior to defense counsel's questioning of the witness and DOJ did not re-open the deposition. As such, Defendants are submitting declarations from these witnesses.

71. Throughout the Relevant Time Period, one or more of the corporate Defendants conducted periodic claims and documentation audits to ensure that services provided by the SNFs were appropriate and properly documented. Ex. 15, Defs.' Resp. to U.S. Interrog. 5; Ex. 4, Defs.' Resp. to U.S. Interrog. 26.; Ex. 12, Lazarus Dep. pp. 60:6-67:17; Ex. 3, HCR Dep. 375:19-379:6,420:13-426:16; Ex. 21, Russell Dep. 292:8-298:1; Ex. 71, Casper Dep. 175:17-179:2; 192:16-194:22, 289:16-290:16; Ex. 69, Mastrangelo Dep. 54:15-21, 55:2-12, 56:14-61:2, 127:13-20; Ex. 1, Cavanaugh Dep. 52:11-55:20. If errors were found in these audits with Medicare claims being non-compliant with CMS rules or guidance, the SNFs remedied the error by reversing or amending claims and by providing education, and if necessary, discipline to its personnel. Ex. 12, Lazarus Dep. 71:13-84:4; Ex. 3 HCR Dep. 249:20-269:4, 269:5-277:10; 279:11-284:10; Ex. 69, Mastrangelo Dep. 220:4-225:5.

72. In 2014, CMS's Innovation Center accepted Optum – Inspiris Services Company to participate in the Bundled Payments for Care Improvement ("BPCI") Model 3 study as part of an initiative under the Affordable Care Act to test payment and service delivery models for post-acute care providers like SNFs, and HCR Healthcare LLC, a wholly owned subsidiary of HCR ManorCare, Inc., was one of Optum's Episode Initiators under that program. Ex. 77, FTI Consulting – Final Baseline Report, July 29, 2014 ("FTI Report"), pp. 1-3; Ex. 58, U.S. Resp.to RFA 56. [redacted].

73. [redacted],

[redacted]. Ex. 78, PIRA Dep. Ex. 97; Ex 77, FTI Report, p. 2; Ex. 58, U.S. Resp. to RFA 57.

74. [redacted]. Ex 77, FTI Report 2-3; Ex. 79, Blair Dep. 33:11-35:7, 77:12-80:20. [redacted]. Ex. 77, FTI Report at 16.

IV. LEGAL STANDARD FOR SUMMARY JUDGMENT

Federal Rule of Civil Procedure 56(a) provides that summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Once a motion for summary judgment is properly made, the opposing party has the burden of showing that a genuine dispute of material fact exists." *Kirkland v. Mabus*, 206 F. Supp. 3d 1073, 1080 (E.D. Va. 2016) (citing *Matsushita*, 475 U.S. at 586-87). "An otherwise properly supported summary judgment motion will not be defeated by the existence of a dispute as to immaterial facts; only disputes over facts that might affect the outcome of the trial will properly preclude the entry of summary judgment." *Lacasse v. Didlake, Inc.*, 194 F. Supp. 3d 494, 500 (E.D. Va. 2016) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "'[I]t is ultimately the nonmovant's burden to persuade [the Court] that there is indeed a dispute of material fact. It must provide more than a scintilla of evidence—and not merely conclusory allegations or speculation—upon which a jury could properly find in its favor.'" *Design Res., Inc. v. Leather Indus. of Am.*, 789 F.3d 495, 500 (4th Cir. 2015) (citation omitted). The quality and quantity of the evidence offered to create a question of fact must be adequate to support a jury verdict. *See Haulbrook,* 252 F.3d at 705-06. The non-moving party may not rely on mere allegations or denials in its own pleadings. *See*

Matsushita, 475 U.S. at 586 n.11.

V. LAW AND ARGUMENT

Given the undisputed material facts in the record, DOJ cannot prove the essential elements of falsity, scienter, or materiality. Nor can it prove its common-law claims, which derive from DOJ's deficient FCA claims. And, even if DOJ could point to sufficient evidence of its claims, the statute of limitations substantially limit their scope. To substantiate its FCA claims, DOJ has the burden to prove: (1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material to the government's decision to pay a claim; and (4) involved a claim made to the government for payment. *See* 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B); *U.S. ex rel. Ahumada v. NISH*, 756 F.3d 268, 280 (4th Cir. 2014); 31 U.S.C. § 3731(d) (DOJ bears the burden of "prov[ing] all essential elements . . . by a preponderance of the evidence"). To meet its burden, DOJ must also prove for each alleged false claim that at least one corporate officer had the requisite knowledge and intent to violate the FCA. *See U.S. v. Scan Health Plan*, No. CV 09-5013, 2017 WL 4564722, at *6-7 (C.D. Cal. Oct. 5, 2017). The concept of collective knowledge is not applicable in FCA cases. *U.S. ex. rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 n.9 (4th Cir. 2003) (rejecting a "collective knowledge" approach that "would allow a plaintiff to prove scienter by piecing together scraps of 'innocent' knowledge held by various corporate officials"). The record does not support any of the four required elements and Defendants are entitled to summary judgment for each of these reasons.

A. DOJ CANNOT ESTABLISH OBJECTIVE FALSITY

The FCA does not define the term "false," but Congress is presumed to have given "its ordinary meaning." *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 566 (2012). As such, the Fourth Circuit requires proof of an "objective falsehood." *Wilson*, 525 F.3d at 377. *See also*

Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 792 (4th Cir. 1999) ("expressions of opinion are not actionable as fraud; fraud may only be found in expressions of fact which (1) admit of being adjudged true or false in a way that (2) admit of empirical verification") (alterations and citations omitted); *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *17 (N.D. Tex. June 20, 2016) ("[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false") (citations and internal quotation marks omitted).

Thus, this case involving the exercise of clinical judgment must be predicated on the presence of an objectively verifiable act at odds with the exercise of that judgment; a "difference of opinion among physicians" or clinicians, "without more, is not enough to show falsity." *U.S. v. AseraCare Inc*., 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016).[7] This overarching principle aligns with CMS's own regulations, which expressly provide that clinical determinations concerning the frequency and duration of rehabilitation therapy needed ***cannot*** constitute material and false statements for any purpose. 42 C.F.R. § 483.20(j)(2); 62 Fed. Reg. 67,174, 67,202-03 (Dec. 23, 1997).

SNFs are statutorily required to provide each patient with "the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-

[7] *Accord Wall*, 2016 WL 3449833, at *17 ("Because a physician must use his or her clinical judgment to determine hospice eligibility, an FCA claim about the exercise of that judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis."); *U.S. v. Paulus*, No. 15-15-DLB-EBA, 2017 WL 908409, at *9 (E.D. Ky. Mar. 07, 2017) (no falsity where DOJ offered only a "*subjective medical opinion*, incapable of confirmation or contradiction") (emphasis in original); *U.S. v. St. Mark's Hosp.*, No. 2:16-cv-00304-JNP-EJF, 2017 WL 237615, at *9 (D. Utah Jan. 19, 2017) ("Opinions, medical judgments, and 'conclusions about which reasonable minds may differ cannot be false' for the purposes of an FCA claim."); *U.S. v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) (no falsity if "reasonable persons can disagree regarding whether the service was properly billed to the Government").

being." 42 U.S.C. § 1395i-3(b)(4)(A)(i); 42 C.F.R. § 483.25. CMS has recognized that "this standard does not always lend itself to easy, objective evaluation." 65 Fed. Reg. 14,289, 14,293 n.26 (Mar. 16, 2000). With regard to services such as therapy, Congress chose not to define "reasonable" or "necessary" through statute, and CMS similarly chose not to do so by regulation. *See* 54 Fed. Reg. 4302, 4304 (Jan. 30, 1989). A "determination of what is 'reasonable and necessary' requires a significant degree of medical judgment." *Almy v. Sebelius*, 679 F.3d 297, 302-03 (4th Cir. 2012) (citation omitted). CMS's regulations explicitly prohibit "rules of thumb" in determining whether any particular therapy is "reasonable and necessary." 42 C.F.R. § 409.32(b).

For Medicare Part A SNF services specifically, the only guidance as to what is "reasonable and necessary" is contained in the Medicare Benefit Policy Manual ("MBPM") Chapter 8, § 30 (2005).[8] But CMS has recognized that treating clinicians in the SNF are best suited to determine what therapy treatments are reasonable and necessary. 76 Fed. Reg. 48,486, 48,513 ("Determinations regarding the appropriate mode of therapy should be made by the therapist based on the needs of each patient."). *See also* Ex. 63, Highmark Dep. 283:5-13; Ex. 8, Maximus Dep. 164:16-165:2; Ex. 80, NGS Dep. 396:9-397:8; Ex. 61, CGS Dep. 407:6-15. Moreover, the determination of reasonable and necessary services required for an individual patient is inherently subjective. *See* Ex. 61, CGS Dep. 426:10-427:11; Ex. 8, Maximus Dep. 162:4-163:16; 174:9-20; Ex. 81, Jessee Dep. 103:5-7; 116:10-22; 140:21-141:20 (medical review involves subjective clinical judgment). Simply put, these subjective clinical judgments about ambiguous terms such as "reasonable" and "necessary" do not and cannot establish objective

[8] Section 30 provides: "The services must be reasonable and necessary for the treatment of a patient's illness or injury, i.e., be consistent with the nature and severity of the individual's illness or injury, the individual's particular medical needs, and accepted standards of medical practice. The services must also be reasonable in terms of duration and quantity."

falsity as required by the FCA.

To sustain its burden DOJ must prove that one or more claims for therapy for the patients in the 180 Patient Sample was false. DOJ's only evidence of falsity for these patients is the clinical opinions from Clearwater.[9] But Clearwater admitted that she offers no opinion on whether any claim was false or fraudulent. Ex. 5, Clearwater Dep. 797:18-19.[10] Instead, she rendered clinical opinions about whether certain therapy for patients in the sample was reasonable, necessary and skilled, even though she was never authorized by the Secretary of Health and Human Services to do so, as required by law. 42 U.S.C. § 1395ddd(a)-(b); Ex. 82, U.S. Third Am. Resp. to Defs.' RFA 1. But "[i]f all that was necessary to prove falsity was to put up a medical expert to review medical records and provide an opinion at odds with that of the [treating clinician or] physician, [healthcare] providers would be subject to potential FCA liability 'any time [DOJ] could find a medical expert who disagreed with the certifying physician's clinical judgment.'" *Wall*, 2016 WL 3449833, at *18 (citation omitted); *see also AseraCare Inc*., 176 F. Supp. at 1283 (entering judgment for defendant where "case boil[ed] down to conflicting views of physicians" over care provided because "the opinion of one medical expert *alone* cannot prove falsity without further evidence of an objective falsehood").[11]

Clearwater testified that she relied on the Social Security Act, CMS regulations, MBPM Chapter 8, MPIM Chapter 6 and ethereal industry standards to determine whether services for

[9] There is no evidence connecting any of the documents referenced in the Complaint or any deposition testimony to the 180 patients in the sample.

[10] As set forth in Defendant's pending Motion to Exclude, Clearwater's opinions are fundamentally flawed and inadmissible. Dkt. 487 ("Mem. to Exclude Clearwater"). As such, they cannot defeat summary judgment for that reason alone. *See U.S. ex rel. Lawson v. Aegis Therapies, Inc.*, No. CV 210-072, 2015 WL 1541491, at *12 (S.D. Ga. March 31, 2015).

[11] Clearwater equated the terms "clinical" and "medical." Ex. 5, Clearwater Dep. 252:21-253:3, 471:1-472:12. *See also* CMS Dep. 62:19-63:21 (CMS position that the terms "clinical" and "medical" are interchangeable).

the 180 patients in the sample were reasonable and necessary. Ex. 57, Clearwater Rep. 25-26; Ex. 5, Clearwater Dep. 55:7-56:13; 57:22-64:5.[12] But that does not turn her clinical decisions into objective evidence that a fraud occurred. Medical judgment is necessarily a part of every individualized patient decision and as noted above, multiple witnesses, including one of the nurses who assisted Clearwater in this case, testified that these determinations are subjective and subject to disagreement. *See* Ex. 61, CGS Dep. 426:10-427:11; Ex. 8, Maximus Dep. 162:4-163:16; 174:9-20; Ex. 81, Jessee Dep. 103:5-7; 116:10-22; 140:21-141:20 (medical review involves subjective clinical judgment).[13]

Nor can any objective falsity be gleaned from any other part of Clearwater's testimony. To make her clinical determinations, she applied criteria for group therapy, modalities, daily minutes, numbers of days of therapy and speech therapy that do not exist in any law, regulation, or CMS guidance. SUMF ¶¶ 48-57; *see also* Mem. to Exclude Clearwater 25-33. Clearwater admitted to this fact. Ex. 5, Clearwater Dep. 51:2-18; 55:4-64:11, 525:5-527:8, 850:14-851:8, 1149:20-1155:18. Further proof of this lies in the three instances where Clearwater denied services that had previously been reviewed as part of the administrative appeal process and determined to be appropriate by a Medicare Contractor or ALJ. SUMF ¶¶ 58-61.

Clearwater's criteria for proper documentation of therapy services are similarly insufficient to prove falsity because during the relevant time period there was no specific

[12] Clearwater has never produced the industry standards she claims to have relied on. Mem. to Exclude Clearwater 41 and Ex. QQ. But in any event, Medicare Part A does not condition payment on industry standards. *See Mikes v. Strauss*, 274 F.3d 687, 701-02 (2nd Cir. 2001); *U.S. ex rel. Johnson v. Golden Gate Nat. Senior Care, LLC*, 223 F. Supp. 3d 882, 897-8 (D. Minn. 2016) (ATPA guidelines are not authoritative guidance for FCA knowledge).

[13] CMS regulations state that the treating clinician has authority to select the modes of therapy. *See* PPS FY 2012 Final Rule 76 Fed. Reg. 48,486, 48,513 (CMS does not dictate the mode of therapy) and 48,514 (the therapist should use her/his best clinical judgment in determining mode and manner of therapy).

guidance to SNFs regarding how to document therapy services. *See Johnson*, 223 F. Supp. 3d at 898 (granting summary judgment to defendants in FCA case based on allegations of failure to properly document therapy where regulations regarding documentation were ambiguous and defendants' interpretation was reasonable). For example, Clearwater contends that group therapy in particular must be ordered by a physician, documented in the plan of care and explained in the therapy notes. Ex. 5, Clearwater Dep. 89:4-8, 661:7-13; Ex. 57, Clearwater Rep. 16. There was never any such requirement in any law, regulation or guidance, and these standards were not applied by the Medicare contractors during the relevant time period. SUMF ¶¶ 48-50.[14] The same analysis applies to Clearwater's decisions to deny modalities, speech therapy for cognition and certain minutes of therapy per day. There was no requirement during the relevant time period that these services be documented in a particular way, and the Medicare contractors did not deny services on these grounds. SUMF ¶¶ 51-57.

Here, there is no "correct amount of therapy," the SNFs accurately reported the therapy that was delivered, and made no false statements in any claim for payment. Moreover, as a matter of law, the SNFs cannot be deemed to have over-delivered therapy based on ambiguous and undefined regulations and the subjective and previously unknown opinions of a single alleged expert witness.

[14] Clearwater pointed to an August 2011 CMS statement in the Federal Register about how group therapy "should" be documented, Ex. 5, Clearwater Dep. 525:5-527:14, which states that "SNFs should include justification for using group therapy as part of the patient's plan of care." 76 Fed. Reg. 48,486, 48,512. But this statement was not published until August 2011, and any new documentation requirements were not effective until October 2011, so it was unknown to Clearwater and Defendants prior to that date. In any event, CMS's statement that the documentation "should" include justification for group therapy is not mandatory and does not create a requirement for payment. *See, e.g., Fife v. Kiawah Island Util., Inc.*, 131 F.3d 133, 1997 WL 780521at *3 (4th Cir. 1997) (table) ("use of the words 'should' – whose plain meaning denotes discretion – and 'shall' – whose plain meaning denotes mandate" and provisions stating regulated agencies "should" meet specified standards were "recommendations, not requirements").

B. DOJ CANNOT ESTABLISH SCIENTER

The FCA requires proof that a defendant committed fraud knowingly—with actual knowledge, in deliberate ignorance, or in reckless disregard of the truth or falsity of information. 31 U.S.C. § 3729(b)(1)(A). This scienter requirement is "rigorous" and must be "strict[ly] enforce[d]" to avoid "open-ended liability." *Escobar*, 136 S. Ct. 1989, 2002 (2016) (citations omitted). *See also Purcell*, 807 F.3d at 287-88.

1. DOJ cannot prove scienter because it has no evidence that a particular employee violated the FCA.

In *Harrison*, the Fourth Circuit held that a corporation's scienter can be proved with evidence that "at least one" employee of the corporation had knowledge of the alleged "wrongful conduct." 352 F.3d at 918 n.9. In so doing, the court specifically rejected the more diffuse "collective knowledge" theory of corporate scienter. *Id.* Further, in *Scan Health*, the district court specified that a corporate defendant "is deemed to have the requisite scienter for fraud *only if the individual corporate officer making the statement* has the requisite level of scienter, *i.e.*, knows that the statement is false, or is at least deliberately reckless as to its falsity, at the time that he or she makes the statement." 2017 WL 4564722 at *5 (emphasis added) (quotations omitted). S*ee also U.S. ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 2015 WL 5178074, at *29 (S.D. Tex. Sept. 3, 2015).

DOJ has produced no evidence of any individual—much less a corporate officer—who possessed "all of the relevant factual information . . . as to the fact[s] or action[s] at issue." *Harrison*, 352 F.3d at 918. That is, there is no one connecting the purported "corporate pressure" scheme to the provision of unskilled, unreasonable, or unnecessary therapy to the 180 Patient Sample, the failure to provide adequate documentation to support that therapy, or any claims for reimbursement for that therapy. *See U.S. ex rel. Conteh v. IKON Office Sols., Inc.*, 27

F. Supp. 3d 80, 88 (D.D.C. 2014) (holding that specific individual employees must be "connect[ed] . . . to the allegedly fraudulent submissions" to prove corporate scienter). DOJ's assertions of fraud, no matter how strongly urged, cannot fill this fatal evidentiary gap.

2. DOJ cannot prove scienter because its liability theories depend on ambiguous legal standards and unknowable practice "standards" applied after the fact by DOJ's expert.

It is well-settled that if "statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007). Thus, "an FCA defendant's reasonable interpretation of an ambiguous regulation belies the scienter necessary to establish a claim of fraud under the FCA." *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879 (8th Cir. 2016) (internal quotations omitted).

Here, DOJ cannot prove that Defendants knowingly violated the FCA because the standards for determining whether therapy is reasonable and necessary are not clearly defined and are subject to more than one reasonable interpretation.[15] The inability to show a "knowing" violation where therapy decisions are involved is underscored by the differences of opinion that arise when professional clinicians determine the need for therapy and how much is appropriate. These differences of opinion are evidenced by (1) the staggering reversal rates of denials of

[15] In fact, reasonable and necessary are among the law's most amorphous and ambiguous terms. *See, e.g., M'Culloch v. Maryland*, 17 U.S. 316, 413 (1819) ("The word 'necessary' . . . has not a fixed character, peculiar to itself" and "is used in various senses"); *GTE Serv. Corp. v. FCC*, 205 F.3d 416, 421 (D.C. Cir. 2000) (finding "necessary" to be "ambiguous"); *Payton v. New York*, 445 U.S. 573, 600 (1980) (noting "amorphous" nature of "reasonable"); *Cmty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 136-37 (2d Cir. 2002) (discussing "[a]mbiguity" of statutory phrase "reasonable and related"); *Alliance for Cmty. Media v. FCC*, 529 F.3d 763, 777 (6th Cir. 2008) ("courts called upon to ascertain the ambiguity of descriptors such as 'reasonable' and 'unreasonable' have found these words subject to multiple constructions").

claims in the administrative process, SUMF ¶ 6; (2) the conflict between the decisions of the Medicare Contractors and ALJs on the one hand and Clearwater on the other as to the claims for C.P., W.C. and S.P., SUMF ¶¶ 58-61; and (3) the testimony of numerous witnesses, including the Medicare Contractors and Clearwater's employee, *supra* at 28.

The same is true for the documentation criteria Clearwater applied. As set forth above, the regulations concerning documentation are unclear and ambiguous, so any violation of those regulations by Defendants or their SNFs could not have been committed "knowingly" under settled law. DOJ has no evidence to the contrary. *See Johnson*, 223 F. Supp. 3d at 898 (granting summary judgment to defendants in FCA case on claims alleging failure to properly document therapy where plaintiff failed to submit evidence that defendants knew the Medicare regulations required specific information in documentation).

3. DOJ cannot prove scienter because the government knew about the alleged fraud and yet continued to pay claims.

DOJ also cannot meet its burden to prove scienter because the undisputed record shows that it knew about the alleged conduct but still paid the claims it now alleges were false. The Fourth Circuit has made clear that "[e]vidence that the government knew about the facts underlying an allegedly false claim can serve to distinguish between the knowing submission of a false claim, which generally is actionable under the FCA, and the submission of a claim that turned out to be incorrect, which generally is not actionable under the FCA." *U.S. ex rel. Ubl v. IIF Data Sols.*, 650 F.3d 445, 452 (4th Cir. 2011). Put another way, "the government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation." *U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (citations omitted).

Here, it defies reason that had the SNFs known that CMS intended to apply the criteria

Clearwater used in this case, they would not have implemented internal documentation requirements consistent with that criteria. Moreover, had the Defendants been aware of the denials and the reasons supporting those denials by AdvanceMed in 2006 and 2007, the SNFs could have implemented policies and procedures to ensure no future denials. The Defendants and the SNFs did not make such changes because the Medicare Contractors continued to pay claims. Instead, CMS and DOJ kept all of these alleged criteria for reimbursement secret until discovery in this case, now seeking to retroactively apply criteria that for the most part still do not exist anywhere in writing.

4. Allegations of "corporate pressure" do not establish scienter of specific false claims.

DOJ has identified bits of documents and deposition testimony it purports prove that the Defendants exerted pressure for more therapy. But DOJ has not identified any evidence to establish a causal link between the supposed pressure and any false statement or false claim as the FCA requires. DOJ has no evidence as to who read or acted upon these documents, if anyone at all. This creates several fatal problems.

First, efforts to "maximize profits" are not evidence of fraud. *U.S. ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 528 (6th Cir. 2012) (reversing FCA judgment for DOJ in similar case and rejecting notion that "a business ought to be punished solely for seeking to maximize profits"); *Ruscher*, 2015 WL 5178074, at *81 ("[E]vidence of a profit motive . . . is not equivalent to evidence of a knowing intention to violate the FCA."). "[P]rudent business practices" are of the same ilk. *Lawson*, 2015 WL 1541491, at *12.

Second, a purported scheme implemented through corporate pressure is not an FCA violation, as a "scheme" is not itself a false or fraudulent claim or statement in violation of the FCA. *See U.S. ex rel. Nathan v. Takeda Pharm. N.A., Inc.*, 707 F.3d 451, 454 (4th Cir. 2013)

("[T]he critical question [in an FCA suit] is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme."); *AseraCare*, 176 F. Supp. 3d at 1283 ("[P]ractices that may be improper, standing alone, are insufficient to show falsity without proof that specific claims were in fact false when submitted to Medicare."); *Wall*, 2016 WL 3449833, at *19 ("[w]ithout evidence linking [the] 'scheme' evidence" to the sample patients, "there is no evidence that the certifying physicians for the [sample] patients were not exercising their best clinical judgments nor that they did not believe the subject patients were terminally ill when they certified them as such, and thus there is no evidence of the falsity required to establish liability").

C. DOJ CANNOT ESTABLISH MATERIALITY

The FCA imposes a "rigorous" and "demanding" requirement that an alleged false claim be material to the government's decision to pay that claim. *Escobar*, 136 S. Ct. at 2002-03. "[M]ateriality 'look[s] to the effect on the *likely or actual behavior* of the recipient of the alleged misrepresentation.'" *Id.* at 2002 (citation omitted). Thus, it is insufficient to simply show "that the Government would have the option to decline to pay if it knew of the defendant's noncompliance" with an applicable statute or regulation. *Id.* at 2003. Rather, "if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* *Escobar*'s materiality standard forecloses DOJ's FCA claims.

1. The government—including DOJ—knew of the underlying allegations for years and did not deny claims.

The undisputed evidence shows that the government knew since at least 2006 about allegations that Defendants' SNFs were allegedly providing unreasonable and unnecessary

therapy and took none of the steps available to it to avoid paying these claims, while specifically instructing AdvanceMed ***not*** to collect overpayments for the claims identified in 2007 as involving unnecessary, unreasonable or unskilled therapy. SUMF ¶¶ 22.

In light of this, DOJ cannot now make the argument that the alleged violations of Medicare rules, regulations and guidance were material to the government's decision to pay.[16] *See U.S. ex rel. Berge v. Bd. of Trs. of the Univ. of Ala.*, 104 F.3d 1453, 1456, 1460, 1462 n.3 (4th Cir. 1997) (holding that "no reasonable jury could have . . . found" materiality where the government continued to fund the grant at issue after relator's allegations had been investigated); *U.S. ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1173-74 (10th Cir. 2016) (holding that where the government did not withhold or suspend payment pending the outcome of its investigations or reserve any rights while attempting to confirm the truth of relators' allegations, but instead paid defendant's invoices in full and without reservation, the inaction was "sufficient to establish the lack of materiality"). *Cf. U.S. v. Triple Canopy, Inc.*, 857 F.3d 174, 178-79 (4th Cir. 2017) (finding evidence of materiality where the government did not renew its contract with defendant and immediately intervened in the underlying *qui tam* litigation when it learned of alleged fraud).

2. No Medicare contractor denied claims for the reasons Clearwater did.

A slightly different materiality analysis applies to Clearwater's specific denials of group therapy, modalities, speech therapy and daily minute reductions. The record is clear that despite actual knowledge of practices regarding the provision and documentation of these services by Defendants' SNFs, no Medicare Contractor, including Clearwater's employer AdvanceMed, ever

[16] Notably, even after the decision to intervene over two years ago CMS still has not taken any remedial action to either stop payment of claims for therapy or to apply the criteria used by Clearwater to claims submitted by Defendants' SNFs from 2012 to the present.

denied or down-coded claims for the reasons Clearwater did here. SUMF ¶¶ 20-21, 49-50, 52-53, 55-56. Thus, to the extent Clearwater's criteria for payment actually existed during the relevant time period (which Defendants dispute), DOJ's inability to identify any instance of these criteria being enforced during the actual processing and review of claims demonstrate that they were not material to the government's decision to pay and, therefore, cannot form the basis of liability under the FCA.

D. DOJ CANNOT PROVE THAT THE CORPORATE DEFENDANTS MADE OR CAUSED FALSE CLAIMS

The Fourth Circuit has made clear that the FCA attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment. *Harrison*, 176 F.3d at 785-86, 792. Therefore, DOJ must prove both the existence of the allegedly false claims and that at least one of the Defendants submitted those claims or caused someone else to do so. *Nathan*, 707 F.3d at 454 ("[T]o trigger liability under the Act, a claim actually must have been submitted to the federal government for reimbursement, resulting in 'a call upon the government fisc."). But there is nothing in the record to satisfy DOJ's burden.

DOJ has no evidence regarding any individuals who actually submitted any individual claim for which they seek hold the Defendants liable. As such, DOJ has no evidence that any of the Defendants actually submitted the claims at issue. Rather, throughout the relevant time period, individual SNFs (which are not named defendants), in some instances with the assistance of a Central Billing Office, submitted claims to Medicare. But the corporate Defendants are not vicariously liable for actions of non-managerial employees unless they had actual knowledge. *See U.S. v. S. Md. HomeHealth Servs.*, 95 F. Supp. 2d 465, 468-69 (D.Md. 2000); *see also U.S. v. Domestic Indus., Inc*., 32 F. Supp. 2d 855, 862 n. 4 (E.D. Va. 1999) (declining to address whether employee's knowledge would be imputed to employer, but noting as very relevant

whether the president of the company knew of the illegal scheme).

On the relevant submission issue, DOJ has only generalized evidence that it believes supports its allegations of a "nationwide scheme" that "originated in HCR ManorCare's corporate offices." Compl. ¶ 6. This evidence comes in the form of training presentations, performance evaluations, emails, and other documents and communications that DOJ asserts is proof of corporate pressure to provide therapy. But none of this evidence is linked to the therapy services provided to a particular Medicare beneficiary or to a specific claim, including any from the 180 Patient Sample. Instead, DOJ hopes to have a trial of a "shotgun" case with no evidence as to how Defendants actually violated the FCA. *See Scan Health*, 2017 WL 4564722 at *7.

E. DOJ'S DERIVATIVE COMMON LAW CLAIMS ARE LEGALLY INSUFFICIENT

DOJ asserts two common law claims that are derivative of its FCA claims—unjust enrichment and payment by mistake. As with the FCA claims, DOJ's common law claims are factually and legally deficient. To prove unjust enrichment, DOJ must show that the "reasonable expectation[s]" of the parties and society demand a return payment by the defendant. *Provident Life & Acc. Ins. Co. v. Waller*, 906 F.2d 985, 993-94 (4th Cir. 1990). To prove payment by mistake, DOJ must show that the government made "payments under an erroneous belief which was material to the decision to pay…." *U.S. v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970) (citing *U.S. v. Wurts*, 303 U.S. 414, 415 (1938)). Where, as here, these claims are bootstrapped to FCA claims based on disputed charges, "[t]he falsity of the disputed [] charges is also an essential element of the DOJ's unjust enrichment [and] payment under mistake of fact [claims]." *U.S. v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 551-52 (E.D. Va. 2003).

Because DOJ's FCA claims fail, its derivative common law claims fail as well. *Mead*, 426 F.2d at 124 (holding that to recover for payment by mistake, the government must show that

it made "payments under an erroneous belief which was material to the decision to pay" to recover under payment by mistake doctrine); *see also Lawson*, 2015 WL 1541491, at *14 (recognizing that unjust enrichment and payment by mistake claims were derivative of the FCA claims and holding that "[b]ecause summary judgment was granted as to the FCA claims, summary judgment is due for these claims as well"); *Prabhu*, 442 F. Supp. 2d at 1035-36 (same).

Further, DOJ cannot prove that the "reasonable expectation[s]" of the parties require Defendants to return the payments, or that the government made payments based on an "erroneous belief" of the facts. As explained above, Defendants' SNFs submitted claims based on reasonable interpretations of ambiguous legal provisions and the government was aware of Defendants' practices and nevertheless continued to make payments. On these facts, DOJ cannot prove its common law claims. *See U.S. v. Medica Rents Co.*, No. 03-11297, 2008 WL 3876307, at *3-4 (5th Cir. Aug. 19, 2008) (holding that DOJ failed to prove common law claims because "there was no misconception or misunderstanding regarding the facts").

F. AT A MINIMUM, SUMMARY JUDGMENT SHOULD BE GRANTED ON EVERY CLAIM NOT INCLUDED IN THE 180 PATIENT SAMPLE

Even if the Court finds material disputes of fact on each of the elements of DOJ's FCA and common law claims relating to the 180 Patient Sample, DOJ has ***no*** evidence of the elements of its claims for the hundreds of thousands of claims outside the sample, to which it seeks to extrapolate liability, and the extrapolated projections of its expert—even if admissible—cannot fill that evidentiary void.

DOJ bears the burden of "prov[ing] all essential elements of the cause of action . . . by a preponderance of the evidence." 31 U.S.C. § 3731(d). Here, as noted, DOJ must prove, on an individualized basis, that each allegedly false claim was objectively false, knowingly made or caused to be made, and material to the government's decision to pay. DOJ lacks the requisite

evidence to establish its claims based on the 180 Patient Sample, and that alone forecloses its claims based on extrapolation, which necessarily depend on proven claims in the sample. Additionally, the only evidence DOJ has offered in support of its extrapolated claims are the opinions of its statistical expert, Donald Edwards, but those are inadmissible for the reasons set forth in Defendants' Memorandum in Support of Their Motion *In Limine* to Exclude Edwards, Dkt. 481 ("Mem. to Exclude Edwards"). But even if Edwards's reports and testimony were admissible, that evidence is not sufficient to prove DOJ's claims in the extrapolated data set. Edwards himself admits that his extrapolation projections are inherently incapable of establishing the elements of the DOJ's FCA claims. Ex. 83, Edwards Dep. 12:16-20; 34:5-13; 312:10-12. Knowledge and intent cannot be extrapolated here where tens of thousands of different clinicians treated nearly half a million patients at over 270 facilities over five and a half years. Ex. 84, Expert Report of Dr. Arnold Barnett, Ph.D., ¶ 18.

Neither the FCA nor any of the statutes governing the Medicare program provides that extrapolation may be used to prove liability or damages under the FCA.[17] Moreover, all but one court handling similar cases related to medical necessity have rejected the use of extrapolation to prove the elements of FCA liability. *See U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 12-cv-3466, 2015 WL 3903675 (D.S.C. June 25, 2015) (holding that statistical sampling was inappropriate to determine "highly fact-intensive" FCA inquiries into whether the care provided to nursing home patients was medically necessary); *Wall*, 2016 WL 3449833, at *10-13 (holding that statistical sampling and extrapolation could not be used to establish FCA liability and

[17] Even in an administrative context, extrapolation is not permitted unless the Secretary of HHS makes a finding that there is a "sustained or high level of payment error." 42 U.S.C. § 1395ddd(f)(3)(A). DOJ's statistical expert testified that he was not aware that this finding had been made. Ex. 83, Edwards Dep. 216:10-15.

damages).[18] Critically, in *Agape* the Fourth Circuit declined to address or overrule the district court's ruling excluding extrapolation of liability and damages. *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330, 336, 341 (4th Cir. 2017) These rulings likewise are fully consistent with analogous U.S. Supreme Court precedent, which rejects "Trial by Formula" where, as here, liability turns on highly individualized determinations. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2561 (2011).[19]

G. DOJ'S UNTIMELY CLAIMS SHOULD BE BARRED

1. Over Half of DOJ's claims are time-barred.

DOJ seeks to impose liability for the time period October 1, 2006 through May 31, 2012. Compl. ¶ 6. But its FCA claims can reach back only to April 10, 2009—6 years before the filing of DOJ's complaint—by operation of the FCA's 6-year statute of limitations. 31 U.S.C. § 3731(b)(2). And DOJ's common-law claims can reach back only to April 10, 2012—3 years before the filing of the DOJ's complaint—by operation of the federal statute of limitations applicable to claims that sound in fraud. 28 U.S.C. § 2415(b).

As noted above, DOJ's common law claims are based on the same alleged fraud underlying its FCA claims. *See* Compl. ¶¶ 221, 224 (alleging in support of common law claims all allegations of fraud supporting its FCA claims). Thus, the 3-year statute of limitations for actions "founded upon a tort" governs here. *See Blusal Meats, Inc. v. U.S.*, 638 F. Supp. 824, 831 (S.D.N.Y. 1986) (holding that "although the government styles its claim as one for 'unjust

[18] The court in *U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014), tentatively found at the outset of the case that DOJ could attempt to prove liability with the extrapolation opinions of its proposed expert. But because the case settled the court in *Life Care* never ruled that DOJ's expert's extrapolation projections could be introduced at trial to prove FCA liability. Mem. to Exclude Edwards 30.

[19] Similarly, because the universe of claims to which DOJ seeks to extrapolate liability includes claims that were previously adjudicated and determined to be appropriate and payable, such as that of [redacted]., SUMF ¶¶58-61, extrapolation in this context would also infringe on the rights to present a res judicata or claim preclusion defense.

enrichment,'" "its substance is that of an action for fraud"), *aff'd*, 817 F.2d 1007 (2d Cir. 1987); *U.S. v. Vicon Const. Co.*, 575 F. Supp. 1578, 1579 (S.D.N.Y. 1983) (applying § 2415(b) to claim sounding in negligence and rejecting plaintiff's attempt to use unjust enrichment to turn a tort claim into a contract action). Partial summary judgment should be granted limiting DOJ's claims accordingly. *See SD3, LLC v. Black & Decker (U.S.), Inc.*, 215 F. Supp. 3d 486, 493 (E.D. Va. 2016) (Hilton, J.) (noting that "courts have repeatedly resolved untimely claims through summary judgment"), *appeals docketed*, No. 16-2317 (Nov. 15, 2016); No. 16-2354 (Nov. 29, 2016) (citation omitted).

2. DOJ's claims do not relate back

DOJ likely will argue that its claims are not time-barred because its Complaint relates back to Ribik's January 7, 2009 complaint. Section 3731(c) of the FCA provides for relation back of a government FCA complaint "to the extent that [it] arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior [qui tam] complaint[.]" This provision does not apply here for several reasons. First, relation back would prejudice the Defendants. Second, sound equitable principles prohibit DOJ from benefiting from its misconduct in connection with the extended limitations period.

a. Relation back would impermissibly prejudice Defendants

The standard for applying relation back under § 3731(c) tracks Rule 15(c)(1)(B) of the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 15(c)(1)(B) (permitting relation back where the later complaint "asserts a claim or defense that arose out of the conduct, transaction, or occurrence" alleged in the earlier complaint). In fact, not only did Congress not displace Rule 15(c) when it enacted § 3731(c)—it copied verbatim Rule 15(c)'s operative text, indicating its intent to incorporate Rule 15(c)'s requirements as applicable to § 3731(c). The legislative history of § 3731(c) confirms this. *See* S. REP. 110-507, at 28-29 (noting that relation back under

provision identical to the later-enacted § 3731(c) is proper "so long as the conditions of [Rule] 15(c)(2) are met").[20] *See also Air Wisconsin Airlines Corp. v. Hoeper*, 134 S. Ct. 852, 861-62 (2014) ("[I]t is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken.") (internal quotation marks omitted).

Consistent with Rule 15(c), relation back under § 3731(c) should not be applied where the defendant would "be prejudiced by the amendment." *Grattan v. Burnett*, 710 F.2d 160, 163 (4th Cir. 1983) (citing *Davis v. Piper Aircraft Corp.*, 615 F.2d 606 (4th Cir. 1980)); *see also Scarborough v. Principi*, 541 U.S. 401, 422 (2004) ("[A] showing of prejudice should preclude operation of the relation-back doctrine in the first place."). Here, Defendants were denied notice of DOJ's claims for at least six years after Ribik filed her complaint and nine years after the government first started investigating Ribik's and related allegations. During that time, witnesses moved on, memories faded, and evidence was potentially lost, including pages of hard copy medical records, the absence of which Clearwater uses to deny and downcode claims. *See Order of R.R. Telegraphers v. Ry. Express Agency*, 321 U.S. 342, 348-49 (1944) ("Statutes of limitation . . . are designed to promote justice by preventing surprises through the revival of claims that have been allowed to slumber until evidence has been lost, memories have faded, and witnesses have disappeared."). This lack of notice, in turn, prevented Defendants and their SNFs from acting promptly to correct the alleged misconduct, all while DOJ did little to advance its investigation, allowing potential damages to accrue. Further, the delay must be considered in light of the government's conduct with respect to the results of the Perrysburg and Grand Rapids

[20] The Senate Report referred to a relation back provision in the proposed False Claims Clarification Act of 2008 (FCCA). The FCCA was not enacted, but its relation back provision and § 3731(c)—enacted a year later—are substantively the same. *Compare* 31 U.S.C. § 3731(c) *with* S. Rep. 110-507, at 42.

audits. SUMF ¶¶ 14, 19-22. Because the government, including DOJ, specifically instructed AdvanceMed not to provide the audit results or seek overpayments, Defendants were deprived of the opportunity to either appeal the denials or change its therapy practices, including regarding documentation. *See Charter Oak Fire Ins. v. Carteret Cnty. Bd. of Comm'rs*, 91 F.3d 129, *2-3 (4th Cir. 1996) (table) (finding that five-month delay in filing claim with insurance company was sufficient basis to deny coverage because insurer was unable to fully investigate the claim).

DOJ's bad-faith conduct, aimed solely at increasing its potential recovery, has severely prejudiced Defendants by depriving them of notice of the allegations against them and a potential limitations defense. *See U.S. ex rel. Mathews v. HealthSouth Corp.*, 332 F.3d 293, 295-96 (5th Cir. 2003) (applying Rule 15 amendment principles and acknowledging that the loss of the statute of limitations defense would prejudice defendant). As a result, Defendants now face an expanded scope of claims, along with the associated penalties and treble damages the FCA provides. Relation back thus should be rejected here. *Intown Props. Mgmt., Inc. v. Wheaton Van Lines, Inc.*, 271 F.3d 164, 170 (4th Cir. 2001) (noting that "courts properly exercise caution in reviewing an application of [Rule 15(c)(2)] that would increase a defendant's exposure to liability").

b. Relation back would inequitably allow DOJ to profit from its misconduct

Relation back is an equitable doctrine subject to equitable principles. *See Scarborough*, 541 U.S. at 418 (the concept of relation back "has its roots in the former federal equity practice") (quotation omitted). Courts therefore have applied equitable principles in applying the relation-back doctrine—including in FCA cases. *See, e.g., Makro Capital of Am., Inc. v. UBS AG*, 543 F.3d 1254, 1260 (11th Cir. 2008) (FCA case, holding that permitting relation back under Rule 15(c) would "promote inequity"); *U.S. ex rel. Health Outcomes Tech. v. Hallmark Health Sys.*

Inc., 409 F. Supp. 2d 43, 50-53 (D. Mass 2006) (rejecting DOJ's relation back argument where "the government operated against the spirit of the" FCA and DOJ "dragged" its investigation "on incessantly" for seven years before intervening). Here, DOJ's misconduct prior to and during this litigation should bar it from benefiting from the equitable relation back principles codified in § 3731(c).

The undisputed record shows that the government had knowledge of the allegations underlying this suit as early as 2005 and no later than 2006. SUMF ¶¶ 12-17. Many of the allegations in DOJ's complaint mirror the reports from AdvanceMed prior to Ribik's filing—suggesting that it had sufficient information to pursue claims before Ribik filed her complaint. *See* Ex. 30 and 33 (medical review results denying claims due to medical necessity); Ex. 35, (referring "entire HCR ManorCare chain" to HHS-OIG). Nevertheless, whether purposely or because of a lack of resources or incompetence, DOJ conducted six years of unilateral discovery after Ribik filed. SUMF ¶¶ 27-43. And it did so by seeking twelve extensions of the original 60-day seal period provided under the FCA, often under the auspices of purportedly legitimate investigative needs, while in fact, the DOJ repeatedly misled the Court by omission. *Id*.

Given this pattern of conduct, the government has forfeited any claim to relation back. On false pretenses, DOJ intentionally manufactured a lengthy period of delay following the filing of Ribik's complaint, expanding the scope of claims against Defendants and increasing the potential recovery. If DOJ is permitted to invoke relation back here, there would be no limit to its ability to increase the punishment for defendants who it believes are violating the law simply by allowing additional alleged violations to accrue while omitting telling the Court of the true reason for the delay. Here, the government did not meet its statutory duty to "diligently" investigate supposed fraud on the government. 31 U.S.C. § 3730(a). This is not how Congress

intended the FCA to operate; how DOJ should carry out its investigative and enforcement responsibilities; or what the public expects of its government.

Permitting relation back here also would allow DOJ unilaterally to toll the statute of limitations and allow damages to accrue indefinitely—all while it continues to pay claims on (and tacitly approve of) the allegedly fraudulent underlying conduct. That result would run counter to the central purpose of the FCA, which serves "to protect the funds and property of the Government from fraudulent claims[,]" *U.S. v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) (internal quotation marks and citation omitted), but ***not*** to allow the government to knowingly permit, for nearly a decade, what it believes to be misappropriation of taxpayer funds. That result also contradicts the "basic policies of all limitations provisions: repose, elimination of stale claims, and certainty about a plaintiff's opportunity for recovery and a defendant's potential liabilities." *Gabelli v. SEC*, 568 U.S. 442, 448 (2013) (internal quotation marks and citation omitted). "Statutes of limitation are 'vital' and 'favored in the law' to protect defendants from stale or fraudulent claims." *Supermarket of Marlinton, Inc. v. Meadow Gold Dairies, Inc.*, 71 F.3d 119, 125 (4th Cir. 1995) (quoting *Wood v. Carpenter*, 101 U.S. 135, 139 (1879)). For each of these reasons, the Court thus can—and should—apply equitable principles to preclude DOJ from benefiting from relation back here. *Makro Capital*, 543 F.3d at 1260; *Health Outcomes*, 409 F. Supp. 2d at 50-53

VI. CONCLUSION

DOJ cannot point to a genuine dispute of material fact on any of the essential elements of its FCA and common-law claims against Defendants. Therefore, no reasonable jury could find for DOJ, and this Court should grant summary judgment in Defendants' favor and dismiss DOJ's complaint with prejudice.

Dated: October 19, 2017

Respectfully submitted,

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I hereby certify that on this 19th day of October 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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